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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/860,844	09/29/97	WEININGER	S GP-100C1

HM22/0507

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EXAMINER	
MARSCHEL, A	
ART UNIT	PAPER NUMBER
1631	20
DATE MAILED: 05/07/01	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/860,844

Applicant(s)

Weininger et al.

Examiner

Ardin Marschel

Art Unit

1631



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Feb 20, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 28, 29, and 49 is/are pending in the applica

~~4) Of the above, Claim(s) 1-27, 30-48, 50, and 51 have been canceled. Claims 28, 29, and 49 will not be considered.~~

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 28, 29, and 49 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' arguments, filed 2/20/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are reiterated. They constitute the complete set presently being applied to the instant application.

Claims 28 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 28 has been amended in the last 2 lines therein to indicate that TBA binds a double stranded nucleic acid. This causes the claim to now contain NEW MATTER. As was noted in the previous office action the TBA binding practice is noted on page 5, lines 19-33, indicates that TBAs bind to a (target binding region)TBR which is made up of a (probe nucleic acid)PNA and a (target nucleic acid)TNA in a PNA-TNA hybrid pair. This PNA-TNA hybrid pair is narrower than a "particular double stranded nucleic acid sequence" as now present in claim 28. A particular double stranded sequence could be reasonably a double stranded

section of a genomic sequence rather than a hybrid made up of a PNA + TNA hybrid. A PNA is disclosed as a probe and not a segment of genomic DNA. This broadening of disclosure is NEW MATTER as support as filed has neither been pointed to by applicants nor found upon reconsideration of the instant specification. This rejection is necessitated by amendment.

Claims 28, 29, and 49 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of what is meant as to a target binding assembly (TBA) are vague and indefinite. The specification at page 5, lines 19-33, seems to indicate that TBAs bind to a (target binding region)TBR which is made up of a (probe nucleic acid)PNA and a (target nucleic acid)TNA in a PNA-TNA hybrid pair as given on page 5, lines 21-22. Thus, an alternative issue to the above NEW MATTER rejection is that the TBA binding in the claims is not commensurate in scope with the TBA binding specifically to PNA+TNA hybrids as cited on said page 5 of the specification. This rejection is reiterated and maintained from the previous office action, mailed 8/15/00.

Claim 29 is vague and indefinite as to the antecedent basis for the "said TBA" and the listed sequences in claim 28 from which it depends. In claim 28 the TBA seems to be either a

purified protein complex or a recombinant vector which expresses a TBA. It is noted that all of the sequences in claim 29 are amino acid sequences. It is not clear what protein complex might be meant. If an expressed TBA is meant then it is expected that an expressed sequence must start with a Methionine as required for expression. It is noted that SEQ ID NOs: 109-113 all lack a starting Met amino acid. It is thus confusing as to what expressed TBA is meant regarding these sequences because of this lack of a required starting Met amino acid. Clarification is requested as to what TBA is meant regarding SEQ ID NOs: 109-113. This rejection was not responded to and is therefore reiterated from the previous office action, mailed 8/15/00.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 28 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Frankel et al. (P/N 5,674,980).

This rejection is reiterated and maintained from the previous office action, mailed 8/15/00. Applicants argue that the Frankel et al. molecule binds to all E2 sites versus the instant invention binding only to individual E2 sites. This selectivity is not seen in the instant claims. Therefore, E2 site binding, albeit all of them, in Frankel et al. is a type of particular double stranded nucleic acid sequence binding as given in the instant claims and thus still suggests the instant invention.

Claim 49 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Essigmann et al. (P/N 5,882,941).

This rejection is maintained and reiterated from the previous office action, mailed 8/15/00. Applicants argue that the selectivity of the instant invention distinguishes it over Essigmann et al. In response this is non-persuasive in the the genomic binding of Essigmann et al. is a type of selectivity over protein or lipid etc., for example. Nothing in the instant claim

49 requires any specific selectivity that is different from the above noted specific binding. Thus, this rejection is maintained as still proper.

The disclosure is objected to because of the following informalities:

The specification contains a section entitled "Brief Description of the Drawings" starting on page 7. These Brief Descriptions are confusing regarding a lack of correspondence between the capitalization or not of designations of Figures and subparts thereof. For example, on page 7, line 25, the designation "Figure 1-IIa" is given but consideration of Figure 1 revealed that there is a subpart IIA but no subpart IIa. On page 7, lines 26-34, similar differences in capitalization or not between the Figures and the Brief descriptions exists and is confusing. Additionally, on page 8, lines 10 and 12, Figures 2a and 2b, respectively, are described. Consideration of the actual Figures revealed that Figures 2A and 2B are present but not Figures 2a and 2b. Applicants are requested to review all of the Brief Figure Descriptions in the specification versus the actual Figures and remove capitalization differences. It is noted that these conflicts also are present in numerous locations elsewhere in the specification. For example, at page 10, line 8, a Figure 5(Ia) is cited but confusingly is Figure 5(IA) in the actual Figure. Also, on page 37, line 26, Figures 12a and 12b are cited

but confusingly there are only Figures 12A and 12B.

Appropriate correction is required.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.



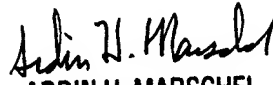
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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 4, 2001

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER